

General

Guideline Title

2013 IDSA clinical practice guideline for vaccination of the immunocompromised host.

Bibliographic Source(s)

Rubin LG, Levin MJ, Ljungman P, Davies EG, Avery R, Tomblyn M, Bousvaros A, Dhanireddy S, Sung L, Keyserling H, Kang I. 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host. Clin Infect Dis. 2014 Feb;58(3):e44-e100. [484 references]
[PubMed](#)

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Quality of evidence (high-quality, moderate-quality, low-quality, very low-quality) and strength of recommendation (strong, weak) ratings are defined at the end of the "Major Recommendations" field.

Note from the National Guideline Clearinghouse (NGC): Tables 2-7 in the original guideline document provide additional recommendations on specific clinical contexts.

Recommendations not addressed by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (CDC ACIP) or the American Academy of Pediatrics (AAP) Committee on Infectious Diseases or that deviate from their recommendations are marked with an asterisk ().*

Recommendations for Responsibility for Vaccination

I. Who Is Responsible for Vaccinating Immunocompromised Patients and Members of Their Household?

1. Specialists who care for immunocompromised patients share responsibility with the primary care provider for ensuring that appropriate vaccinations are administered to immunocompromised patients (strong, low).*
2. Specialists who care for immunocompromised patients share responsibility with the primary care provider for recommending appropriate vaccinations for members of immunocompromised patients' household (strong, very low).*

Recommendations for Timing of Vaccination

II. When Should Vaccines Be Administered to Immunocompetent Patients in Whom Initiation of Immunosuppressive Medications Is Planned?

3. Vaccines should be administered prior to planned immunosuppression if feasible (strong, moderate).

4. Live vaccines should be administered ≥ 4 weeks prior to immunosuppression (strong, low) and should be avoided within 2 weeks of initiation of immunosuppression (strong, low).*
5. Inactivated vaccines should be administered ≥ 2 weeks prior to immunosuppression (strong, moderate).

Recommendations for Vaccines for Household Members of Immunocompromised Patients

III. Which Vaccines Can Be Safely Administered to Individuals Who Live in a Household with Immunocompromised Patients? What Precautions Should Immunocompromised Patients Observe after Vaccination of Household Members?

6. Immunocompetent individuals who live in a household with immunocompromised patients can safely receive inactivated vaccines based on the CDC–ACIP's annually updated recommended vaccination schedules for children and adults (hereafter, CDC annual schedule; strong, high) or for travel (strong, moderate).
7. Individuals who live in a household with immunocompromised patients age ≥ 6 months should receive influenza vaccine annually (strong, high). They should receive either:
 - a. Inactivated influenza vaccine (IIV; strong, high) or
 - b. Live attenuated influenza vaccine (LAIV) provided they are healthy, not pregnant, and aged 2–49 years (strong, low). Exceptions include individuals who live in a household with an immunocompromised patient who was a hematopoietic stem cell transplant (HSCT) recipient within 2 months after transplant or with graft vs host disease (GVHD) or is a patient with severe combined immune deficiency (SCID).* In these exceptions, LAIV should not be administered (weak, very low) or, if administered, contact between the immunocompromised patient and household member should be avoided for 7 days (weak, very low).
8. Healthy immunocompetent individuals who live in a household with immunocompromised patients should receive the following live vaccines based on the CDC annual schedule: combined measles, mumps, and rubella (MMR) vaccines (strong, moderate); rotavirus vaccine in infants aged 2–7 months (strong, low); varicella vaccine (VAR; strong, moderate); and zoster vaccine (ZOS; strong, moderate). Also, these individuals can safely receive the following vaccines for travel: yellow fever vaccine (strong, moderate) and oral typhoid vaccine (strong, low).
9. Oral polio vaccine (OPV) should *not* be administered to individuals who live in a household with immunocompromised patients (strong, moderate).
10. Highly immunocompromised patients should avoid handling diapers of infants who have been vaccinated with rotavirus vaccine for 4 weeks after vaccination (strong, very low).
11. Immunocompromised patients should avoid contact with persons who develop skin lesions after receipt VAR or ZOS until the lesions clear (strong, low).

Vaccines for International Travel

IV. Which Vaccines Can Be Administered to Immunocompromised Persons Contemplating International Travel?

12. Clinicians may administer inactivated vaccines indicated for travel based on the CDC annual schedule for immunocompetent adults and children (strong, low).
13. Yellow fever vaccine generally should *not* be administered to immunocompromised persons (strong, moderate). If travel to an endemic area cannot be avoided, vaccination can be considered in the following minimally immunocompromised human immunodeficiency virus (HIV)–infected individuals:
 - a. Asymptomatic HIV-infected adults with CD4 T-cell lymphocyte count ≥ 200 cells/mm³ (weak, low)
 - b. Asymptomatic HIV-infected children aged 9 months–5 years with CD4 T-cell lymphocyte percentages of ≥ 15 (weak, very low).
14. With certain exceptions (e.g., yellow fever vaccine and MMR vaccine in certain HIV-infected patients [see recommendation 13 and "Recommendations for Vaccination of HIV-infected Adults, Adolescents, and Children" section] and in certain HSCT patient [see "Recommendations for Vaccination of Hematopoietic Stem Cell Transplant Patients"]), live vaccines should not be given to immunocompromised persons (strong, low).

Recommendations for Varicella and Zoster Vaccines in Immunocompromised Patients

VAR

V. Should Immunocompromised Patients or Those Scheduled to Receive Immune Suppressive Therapy Receive VAR?

15. VAR should be given to immunocompetent patients without evidence of varicella immunity (i.e., age-appropriate varicella vaccination, serologic evidence of immunity, clinician-diagnosed or -verified history of varicella or zoster, or laboratory-proven varicella or zoster; strong, moderate) if it can be administered ≥ 4 weeks before initiating immunosuppressive therapy (strong, low).

16. A 2-dose schedule of VAR, separated by >4 weeks for patients aged ≥13 years and by ≥3 months for patients aged 1–12 years, is recommended if there is sufficient time prior to initiating immunosuppressive therapy (strong, low).
17. VAR should *not* be administered to highly immunocompromised patients. However, certain categories of patients (e.g., patients with HIV infection without severe immunosuppression or with a primary immune deficiency disorder without defective T-cell-mediated immunity, such as primary complement component deficiency disorder or chronic granulomatous disease [CGD]) should receive VAR, adhering to a 2-dose schedule separated by a 3-month interval (strong, moderate).
18. VAR can be considered for patients without evidence of varicella immunity (defined in recommendation 16) who are receiving long-term, low-level immunosuppression (weak, very low).*
19. VAR should be administered to eligible immunocompromised patients as the single antigen product, not VAR combined with MMR vaccine (strong, low).

Herpes Zoster Vaccine

VI. Should Immunocompromised Patients or Those Who Will Undergo Immunosuppression Receive Herpes Zoster Vaccine?

20. ZOS should be given to patients aged ≥60 years if it can be administered ≥4 weeks before beginning highly immunosuppressive therapy (strong, low).
21. ZOS should be considered for varicella-positive patients (i.e., persons with a history of varicella or zoster infection or who are varicella–zoster virus [VZV] seropositive with no previous doses of VAR) aged 50–59 years if it can be administered ≥4 weeks before beginning immunosuppressive therapy (weak, low).*
22. ZOS should be administered to patients aged ≥60 years who are receiving therapy considered to induce a low level of immunosuppression (strong, low).
23. ZOS should *not* be administered to highly immunocompromised patients (strong, very low).

Recommendations for Influenza Vaccine in the Immunocompromised Host

VII. Should Immunocompromised Persons Receive Influenza Vaccine?

24. Annual vaccination with IIV is recommended for immunocompromised patients aged ≥6 months (strong, moderate) except for patients who are very unlikely to respond (although unlikely to be harmed by IIV), such as those receiving intensive chemotherapy* (strong, low) or those who have received anti-B-cell antibodies within 6 months* (strong, moderate).
25. LAIV should *not* be administered to immunocompromised persons (weak, very low).

Recommendations for Vaccination of Patients with Primary Immunodeficiency Disorders

VIII. Which Vaccines Should Be Administered to Patients with Primary (Congenital) Complement Deficiencies?

26. Patients with primary complement deficiencies should receive all routine vaccines based on the CDC annual schedule; none are contraindicated (strong, low).
27. Patients with primary complement deficiencies and who are
 - a. Aged 2–5 years should receive 1 dose of 13-valent pneumococcal conjugate vaccine (PCV13) if they have received 3 doses of PCV (either 7-valent PCV [PCV7] or PCV13) before age 24 months and 2 doses of PCV13 (8 weeks apart) if they have received an incomplete schedule of ≤2 doses of PCV7 (PCV7 or PCV13) before age 24 months (strong, low).
 - b. Aged 6–18 years with a classic pathway (C1, C2, C3, C4), alternate pathway, or severe mannan-binding lectin (MBL) deficiency who have not received PCV13 should receive a single dose of PCV13 (strong, very low).
 - c. Aged ≥19 years with a classic pathway (C1, C2, C3, C4), alternate pathway, or severe MBL deficiency who are PCV13 naive should receive a single dose of PCV13 (strong, very low). For those who received pneumococcal polysaccharide vaccine-23 (PPSV23), PCV13 should be administered ≥1 year after the last PPSV23 dose (weak, low).
28. Patients aged ≥2 years with an early classic pathway, alternate pathway, or severe MBL deficiency should receive PPSV23 ≥8 weeks after PCV13, and a second dose of PPSV23 should be given 5 years later (strong, low).
29. Patients with primary complement deficiencies should receive conjugate meningococcal vaccine. A 4-dose series of bivalent meningococcal conjugate vaccine and *Haemophilus influenzae* type b conjugate vaccine (HibMenCY; MenHibrix, GlaxoSmithKline) should be administered at age 2, 4, 6, and 12–15 months for children aged 6 weeks–18 months (strong, low) or a 2-dose primary series of meningococcal conjugate vaccine, quadrivalent (MCV4) should be administered to patients with primary complement component deficiency at age 9 months–55 years (MCV4-D [Menactra, Sanofi Pasteur] for those aged 9–23 months; MCV4-D or MCV4-CRM [Menveo, Novartis; CRM, diphtheria CRM₁₉₇ protein] for those aged 2–54 years; strong, low). For persons aged >55 years, MPSV4 (meningococcal polysaccharide vaccine, quadrivalent) should be administered if they have not received MCV4 and MCV4 should be administered if they have received MCV4 (strong, low). For patients aged 9–23 months, the doses should be administered 3 months apart; for patients aged ≥2 years, the doses should be administered 2 months apart. MCV4-

D should be administered ≥ 4 weeks after a dose of PCV13 because of a reduced antibody response to some pneumococcal serotypes when MCV4-D and PCV7 are administered simultaneously (strong, low).

30. Patients with a primary complement component deficiency should be revaccinated with MCV4 (or MPSV4 for those aged >55 years who have not received MCV4) every 5 years (strong, low).

IX. Which Vaccines Should Be Administered to Patients with Phagocytic Cell Deficiencies (e.g., CGD, Leukocyte Adhesion Deficiency, Chediak–Higashi Syndrome)?

31. Patients with phagocytic cell deficiencies should receive all inactivated vaccines based on the CDC annual schedule (strong, low). Children aged 2–5 years should receive PCV13 as in recommendation 27a (weak, very low).
32. Patients aged ≥ 6 years with phagocytic cell deficiencies other than CGD (unless patient with CGD is receiving immunosuppressive medication) should receive PCV13 as in recommendations 27b and 27c (weak, very low).
33. Patients aged ≥ 2 years with phagocytic cell deficiencies other than CGD (unless patient with CGD is receiving immunosuppressive medication) should receive PPSV23 ≥ 8 weeks after receipt of PCV13, and a second dose of PPSV23 should be given 5 years later (weak, low).
34. Live bacterial vaccines, such as bacillus Calmette–Guérin (BCG) or oral typhoid vaccine, should *not* be administered to patients with a phagocytic cell defect (strong, moderate).
35. Live viral vaccines should be administered to patients with CGD and to those with congenital or cyclical neutropenia (weak, low).
36. Live viral vaccines should *not* be administered to patients with leukocyte adhesion deficiency, defects of cytotoxic granule release such as Chediak–Higashi syndrome (see question XIII, recommendation 50) or any other undefined phagocytic cell defect (strong, low).

X. Which Vaccines Should Be Administered to Patients with Innate Immune Defects That Result in Defects of Cytokine Generation/Response or Cellular Activation (e.g., Defects of the Interferon- γ /Interleukin-12 Axis)?

37. Patients with innate immune defects that result in defects of cytokine generation/response or cellular activation should receive all inactivated vaccines based on the CDC annual schedule (strong, very low).
38. For patients with innate immune defects that result in defects of cytokine generation/response or cellular activation, PCV13 should be administered as in recommendations 27a–c (weak to strong, very low to low).
39. The advice of a specialist should be sought regarding individual conditions concerning use of live vaccines in patients with innate immune defects that result in defects of cytokine generation/response or cellular activation/inflammation generation (strong, low).
40. Live bacterial vaccines should *not* be administered to patients with defects of the interferon- γ /interleukin-12 (IFN- γ /IL-12) pathways (strong, moderate).
41. Live viral vaccines should *not* be administered to patients with defects of IFN (alpha or gamma) production (strong, low).

XI. Which Vaccines Should Be Administered to Patients with Minor Antibody Deficiencies?

42. Patients with immunoglobulin (Ig)A deficiency or specific polysaccharide antibody deficiency (SPAD) should receive all routine vaccinations based on the CDC annual schedule, provided that other components of their immune systems are normal (strong, low).
43. Children with SPAD or ataxia–telangiectasia should receive PCV13 as described in recommendations 27a–c (weak to strong, very low to low). Those aged ≥ 2 years should receive PPSV23 ≥ 8 weeks after indicated doses of PCV13, and a second dose should be given 5 years later (strong, low).
44. Monitoring of vaccine responses can be useful for assessing the degree of immunodeficiency of patients with minor antibody deficiencies and level of protection (weak, moderate).
45. OPV should *not* be administered to IgA-deficient patients (strong, low).

XII. Which Vaccines Should Be Administered to Patients with Major Antibody Deficiencies Who Are Receiving Immunoglobulin Therapy?

46. Inactivated vaccines other than IIV are not routinely administered to patients with major antibody deficiencies during immunoglobulin therapy (strong, low).
 - a. For patients with suspected major antibody deficiencies, all inactivated vaccines can be administered as part of immune response assessment prior to immunoglobulin therapy (strong, low).
47. IIV can be administered to patients with major antibody deficiencies and some residual antibody production (weak, low).
48. Live OPV should *not* be administered to patients with major antibody deficiencies (strong, moderate).
49. Live vaccines (other than OPV) should *not* be administered to patients with major antibody deficiencies (weak, low).*

XIII. Which Vaccines Should Be Administered to Patients with Combined Immunodeficiencies?

50. For patients with suspected combined immunodeficiencies, all inactivated vaccines can be administered as part of the immune response assessment prior to commencement of immunoglobulin therapy (strong, low).
 - a. For patients with combined immunodeficiencies who are receiving immunoglobulin therapy, inactivated vaccines should *not* be

routinely administered (strong, low).

51. For patients with combined immunodeficiencies and residual antibody production potential, IIV can be administered (weak, very low).
52. Children with partial DiGeorge syndrome (pDGS) should undergo immune system assessment with evaluation of lymphocyte subsets and mitogen responsiveness in order to determine whether they should be given live viral vaccines. Those with ≥ 500 CD3 T cells/mm³, ≥ 200 CD8 T cells/mm³, and normal mitogen response should receive MMR vaccine and VAR (weak, low).*
53. Patients with SCID, DGS with a CD3 T-cell lymphocyte count < 500 cells/mm³, other combined immunodeficiencies with similar CD3 T-cell lymphocyte counts, Wiskott–Aldrich syndrome, or X-linked lymphoproliferative disease and familial disorders that predispose them to hemophagocytic lymphohistiocytosis should *avoid* all live vaccines (strong, moderate).

Recommendations for Vaccination of HIV-Infected Adults, Adolescents, and Children

XIV. Which Inactivated Vaccines Should Be Administered to HIV-Infected Patients?

54. HIV-infected patients should be vaccinated according to the CDC annual schedule for the following inactivated vaccines: IIV (strong, high); PCV13 in patients aged < 2 years (strong, moderate); *H. influenzae* type b conjugate (Hib) vaccine (strong, high); diphtheria toxoid, tetanus toxoid, acellular pertussis (DTaP) vaccine (strong, moderate); tetanus toxoid, reduced diphtheria toxoid, and reduced acellular pertussis (Tdap) vaccine (strong, very low); tetanus toxoid, reduced diphtheria toxoid (Td) vaccine (strong, low); hepatitis B (HepB) vaccine (strong, moderate); hepatitis A (HepA) vaccine (strong, moderate); inactivated poliovirus (IPV) vaccine (strong, moderate); and quadrivalent human papillomavirus (HPV4) vaccine* in females and males aged 11–26 years (strong, very low) with additions noted below.
55. PCV13 should be administered to HIV-infected patients aged ≥ 2 years as in recommendations 27a–c (strong, low to moderate).
56. PPSV23 should be administered to HIV-infected children aged ≥ 2 years of age who have received indicated doses of PCV (strong, moderate), HIV-infected adults with CD4 T-lymphocyte counts of ≥ 200 cells/mm³ (strong, moderate), and HIV-infected adults with CD4 T-lymphocyte counts of < 200 cells/mm³ (weak, low). PPSV23 should be given ≥ 8 weeks after indicated dose(s) of PCV13, and a second dose of PPSV23 should be given 5 years later (strong, low).
57. HIV-infected children who are aged > 59 months and have not received Hib vaccine should receive 1 dose of Hib vaccine (strong, low). Hib vaccine is *not* recommended for HIV-infected adults (weak, low).
58. HIV-infected children aged 11–18 years should receive a 2-dose primary series of MCV4 2 months apart (strong, moderate). A single booster dose (third dose) should be given at age 16 years if the primary series was given at age 11 or 12 years and at age 16–18 years if the primary series was given at age 13–15 years (strong, low). If MCV4 is administered to HIV-infected children aged 2–10 years because of risk factors for meningococcal disease, a 2-dose primary series of MCV4 should be administered with a 2-month interval between doses, and a booster dose should be given 5 years later (strong, very low).
59. HIV-infected patients should receive the HepB vaccine series (strong, moderate), with consideration of high-dose HepB vaccine (40 μ g/dose) for adults (weak, moderate) and adolescents* (weak, low). One to 2 months after completion, patients should be tested for anti-HBs (antibodies to HepB surface antigen; strong, low). If a postvaccination anti-HB concentration of ≥ 10 mIU/mL is not attained, a second 3-dose series of HepB vaccine (strong, low; alternative: 1 dose of HepB vaccine after which anti-HBs is tested*), using standard dose (strong, moderate) or high dose (40 μ g*; weak, low) for children and high dose for adolescents* and adults (strong, low), should be administered.
60. HepB vaccine containing 20 μ g of HepB surface antigen (HBsAg) combined with HepA vaccine (HepA–HepB; Twinrix), 3-dose series, can be used for primary vaccination of HIV-infected patients aged ≥ 12 years (strong, moderate).*
61. Internationally adopted HIV-infected children who have received doses of OPV should receive a total of 4 doses of a combination of OPV and IPV vaccine (strong, low).
62. HPV4 vaccine is recommended over bivalent human papillomavirus (HPV2) vaccine because HPV4 vaccine prevents genital warts (strong, low),* although there are no data on differences between the vaccines for preventing cervical dysplasia in HIV-infected women.

XV. Should Live Vaccines Be Administered to HIV-Infected Patients?

63. HIV-exposed or -infected infants should receive rotavirus vaccine according to the schedule for uninfected infants (strong, low).
64. HIV-infected patients should *not* receive LAIV (weak, very low).
65. MMR vaccine should be administered to clinically stable HIV-infected children aged 1–13 years without severe immunosuppression (strong, moderate) and HIV-infected patients aged ≥ 14 years without measles immunity and with a CD4 T-cell lymphocyte count ≥ 200 /mm³ (weak, very low).
66. HIV-infected children with a CD4 T-cell percentage < 15 (strong, moderate) or patients aged ≥ 14 years with a CD4 T-cell lymphocyte count < 200 cells/mm³ should *not* receive MMR vaccine (strong, moderate).

67. HIV-infected patients should *not* receive quadrivalent MMR-varicella (MMRV) vaccine (strong, very low).
68. Varicella-nonimmune, clinically stable HIV-infected patients aged 1–8 years with $\geq 15\%$ CD4 T-lymphocyte percentage (strong, high), aged 9–13 years with $\geq 15\%$ CD4 T-lymphocyte percentage (strong, very low), and aged ≥ 14 years with CD4 T-lymphocyte counts ≥ 200 cells/mm³ should receive VAR (strong, very low). The 2 doses should be separated by ≥ 3 months (strong, moderate).

Recommendations for Vaccination in Patients with Cancer

XVI. What Vaccines Should Be Given to Patients with Cancer?

69. Patients aged ≥ 6 months with hematological malignancies (strong, moderate) or solid tumor malignancies (strong, low) *except* those receiving anti-B-cell antibodies* (strong, moderate) or intensive chemotherapy, such as for induction or consolidation chemotherapy for acute leukemia (weak, low), should receive IIV annually.*
70. PCV13 should be administered to newly diagnosed adults with hematological (strong, very low) or solid malignancies (strong, very low) and children with malignancies (strong, very low) as described in recommendations 27a-c. PPSV23 should be administered to adults and children aged ≥ 2 years (strong, low) at least 8 weeks after the indicated dose(s) of PCV13.
71. Inactivated vaccines (other than IIV) recommended for immunocompetent children in the CDC annual schedule can be considered for children who are receiving maintenance chemotherapy (weak, low). However, vaccines administered during cancer chemotherapy should *not* be considered valid doses (strong, low) unless there is documentation of a protective antibody level (strong, moderate).
72. Live viral vaccines should *not* be administered during chemotherapy (strong, very low to moderate).
73. Three months after cancer chemotherapy, patients should be vaccinated with inactivated vaccines (strong, very low to moderate) and the live vaccines for varicella (weak, very low); measles, mumps, and rubella (strong, low); and measles, mumps, and rubella–varicella (weak, very low) according to the CDC annual schedule that is routinely indicated for immunocompetent persons. In regimens that included anti-B-cell antibodies, vaccinations should be delayed at least 6 months (strong, moderate).

Recommendations for Vaccination of Hematopoietic Stem Cell Transplant Patients

XVII. Should HSCT Donors and Patients Be Vaccinated before Transplantation?

74. The HSCT donor should be current with routinely recommended vaccines based on age, vaccination history, and exposure history according to the CDC annual schedule (strong, high). However, administration of MMR, MMRV, VAR, and ZOS vaccines should be avoided within 4 weeks of stem cell harvest (weak, very low). Vaccination of the donor for the benefit of the recipient is *not* recommended (weak, moderate).
75. Prior to HSCT, candidates should receive vaccines indicated for immunocompetent persons based on age, vaccination history, and exposure history according to the CDC annual schedule if they are not already immunosuppressed (strong, very low to moderate) and when the interval to start of the conditioning regimen is ≥ 4 weeks for live vaccines (strong, low) and ≥ 2 weeks for inactivated vaccines (strong, moderate).
76. Nonimmune HSCT candidates aged ≥ 12 months should receive VAR (as a 2-dose regimen if there is sufficient time) if they are not immunosuppressed and when the interval to start the conditioning regimen is ≥ 4 weeks (strong, low).

XVIII. Which Vaccines Should Be Administered to Adults and Children after HSCT?

77. One dose of IIV should be administered annually (strong, moderate) to persons aged ≥ 6 months starting 6 months after HSCT (strong, moderate) and starting 4 months after if there is a community outbreak of influenza as defined by the local health department (strong, very low). For children aged 6 months–8 years who are receiving influenza vaccine for the first time, 2 doses should be administered (strong, low).
78. Three doses of PCV13 should be administered to adults and children starting at age 3–6 months after HSCT (strong, low). At 12 months after HSCT, 1 dose of PPSV23 should be given provided the patient does not have chronic GVHD (strong, low). For patients with chronic GVHD, a fourth dose of PCV13 can be given at 12 months after HSCT (weak, very low).*
79. Three doses of Hib vaccine should be administered 6–12 months after HSCT (strong, moderate).
80. Two doses of MCV4 should be administered 6–12 months after HSCT to persons aged 11–18 years, with a booster dose given at age 16–18 years for those who received the initial post-HSCT dose of vaccine at age 11–15 years (strong, low).
81. Three doses of tetanus/diphtheria-containing vaccine should be administered 6 months after HSCT (strong, low). For children aged < 7 years, 3 doses of DTaP should be administered (strong, low). For patients aged ≥ 7 years, administration of 3 doses of DTaP should be considered (weak, very low).* Alternatively, a dose of Tdap vaccine should be administered followed by either 2 doses of diphtheria toxoid combined with tetanus toxoid (DT) (weak, moderate)* or 2 doses of Td vaccine (weak, low).
82. Three doses of HepB vaccine should be administered 6–12 months after HSCT (strong, moderate). If a postvaccination anti-HBs concentration of ≥ 10 mIU/mL is not attained, a second 3-dose series of HepB vaccine (strong, low; alternative: 1 dose of HepB vaccine after which anti-HBs is tested*), using standard dose (strong, moderate) or high dose (40 μ g*; weak, low) for children and high dose for adolescents* and adults (strong, low), should be administered.

83. Three doses of IPV vaccine should be administered 6–12 months after HSCT (strong, moderate).
84. Consider administration of 3 doses of HPV vaccine 6–12 months after HSCT for female patients aged 11–26 years and HPV4 vaccine for males aged 11–26 years (weak, very low).
85. Do *not* administer live vaccines to HSCT patients with active GVHD or ongoing immunosuppression (strong, low).
86. A 2-dose series of MMR vaccine should be administered to measles-seronegative adolescents and adults (strong, low) and to measles-seronegative children (strong, moderate) 24 months after HSCT in patients with neither chronic GVHD nor ongoing immunosuppression and 8–11 months (or earlier if there is a measles outbreak) after the last dose of immune globulin intravenous (IGIV).
87. A 2-dose series of VAR should be administered 24 months after HSCT to varicella seronegative patients with neither GVHD nor ongoing immunosuppression and 8–11 months after the last dose of IGIV (strong, low).

Recommendations for Vaccination of Solid Organ Transplant Recipients

XIX. For Adult and Child Solid Organ Transplant Candidates and Living Donors, Which Vaccines Should Be Administered During Pretransplant Evaluation?

88. Living donors should be current with vaccines based on age, vaccination history, and exposure history according to the CDC annual schedule (strong, high); MMR, MMRV, VAR, and ZOS vaccine administration should be avoided within 4 weeks of organ donation (weak, very low). Vaccination of donors solely for the recipient's benefit is generally not recommended (weak, low).
89. Adults and children with chronic or end-stage kidney, liver, heart, or lung disease, including solid organ transplant (SOT) candidates, should receive all age-, exposure history-, and immune status-appropriate vaccines based on the CDC annual schedule for immunocompetent persons (strong, moderate).
90. Adult SOT candidates; adults with end-stage kidney disease; and pediatric patients who are SOT candidates; are aged <6 years and have end-stage kidney, heart, or lung disease; or are aged 6–18 years and have end-stage kidney disease should receive PCV13 as in recommendations 27a-c (strong, very low).
91. Adults and children aged ≥ 2 years who are SOT candidates or have end-stage kidney disease should receive PPSV23 if they have not received a dose within 5 years and have not received 2 lifetime doses (strong, moderate). Patients with end-stage kidney disease should receive 2 lifetime doses 5 years apart (strong, low). Adults and children aged ≥ 2 years with end-stage heart or lung disease as well as adults with chronic liver disease, including cirrhosis, should receive a dose of PPSV23 if they have never received a dose (strong, low). When both PCV13 and PPSV23 are indicated, PCV13 should be completed 8 weeks prior to PPSV23 (strong, moderate).
92. Anti-HBs–negative SOT candidates should receive the HepB vaccine series (strong, moderate) and, if on hemodialysis and aged ≥ 20 years, they should receive the high-dose (40 μ g) HepB vaccine series (strong, moderate). If a postvaccination anti-HBs concentration of ≥ 10 mIU/mL is not attained, a second 3-dose series of HepB vaccine (strong, low; alternative: 1 dose of HepB vaccine after which anti-HBs is tested*) should be administered, using standard dose (strong, moderate) or high dose* for children (weak, low) and high dose for adolescents* and adults (strong, low). HepA-unvaccinated, -undervaccinated, or -seronegative SOT candidates (particularly liver transplant candidates) aged 12–23 months (strong, moderate) and ≥ 2 years (strong, moderate) should receive a HepA vaccine series.
93. Combined HepA–HepB vaccine can be used for SOT candidates aged ≥ 12 years of age* in whom both vaccines are indicated (strong, moderate).
94. The HPV vaccine series should be administered to SOT candidates aged 11–26 years (strong, low-moderate).
95. SOT candidates aged 6–11 months can receive MMR vaccine if they are not receiving immunosuppression and if transplantation is not anticipated within 4 weeks (weak, very low). If transplantation is delayed (and the child is not receiving immunosuppression), the MMR vaccine should be repeated at 12 months (strong, moderate).
96. The VAR should be administered to SOT candidates without evidence of varicella immunity (as defined in recommendation 16) if they are not receiving immunosuppression and if transplantation is not anticipated within 4 weeks (strong, moderate). The VAR can be administered to varicella-naïve SOT candidates aged 6–11 months who are not immunosuppressed provided the timing is ≥ 4 weeks prior to transplant (weak, very low). * Optimally, 2 doses should be administered ≥ 3 months apart (strong, low).
97. SOT candidates aged ≥ 60 years (strong, moderate) and varicella-positive candidates (as defined in recommendation 22) aged 50–59 years (weak, low)* who are not severely immunocompromised should receive ZOS if transplantation is *not* anticipated within 4 weeks.

XX. Which Vaccines Should Be Administered to SOT Recipients?

98. Vaccination should be withheld from SOT recipients during intensified immunosuppression, including the first 2-month posttransplant period, because of the likelihood of inadequate response (strong, low). However, IIV can be administered ≥ 1 month after transplant during a community influenza outbreak (weak, very low).

99. Standard age-appropriate inactivated vaccine series should be administered 2 to 6 months after SOT based on the CDC annual schedule (strong, low to moderate), including IIV (strong, moderate).
100. PCV13 should be administered 2 to 6 months after SOT if not administered before SOT, with the timing based on the patient's degree of immunosuppression, as described in recommendations 27a–c (strong, very low to moderate).
101. For SOT patients aged ≥ 2 years, 1 dose of PPSV23 should be administered 2 to 6 months after SOT, with the timing based on the patient's degree of immunosuppression, and ≥ 8 weeks after indicated doses of PCV13, if not given within 5 years and if the patient has received no more than 1 previous lifetime dose (strong, moderate).
102. HepB vaccine should be considered for chronic HepB-infected recipients 2 to 6 months after liver transplant in an attempt to eliminate the lifelong requirement for HepB immune globulin (HBIG; weak, low).*
103. MMR vaccine and VAR should generally *not* be administered to SOT recipients because of insufficient safety and effectiveness data (strong, low), except for varicella in children without evidence of immunity (as defined in recommendation 15) who are renal or liver transplant recipients, are receiving minimal or no immunosuppression, and have no recent graft rejection (weak, moderate).*
104. Vaccination should *not* be withheld because of concern about transplant organ rejection (strong, moderate).

Recommendations for Vaccination of Patients with Chronic Inflammatory Diseases on Immunosuppressive Medications

XXI. Which Vaccines Should Be Administered to Patients with Chronic Inflammatory Diseases Maintained on Immunosuppressive Therapies?

105. Inactivated vaccines, including IIV, should be administered to patients with chronic inflammatory illness treated (strong, low-moderate) or about to be treated (strong, moderate) with immunosuppressive agents as for immunocompetent persons based on the CDC annual schedule.
106. PCV13 should be administered to adults and children with a chronic inflammatory illness that is being treated with immunosuppression as described in the standard schedule for children and in recommendations 27a–c (strong, very low-moderate).
107. PPSV23 should be administered to patients aged ≥ 2 years with chronic inflammatory illnesses with planned initiation of immunosuppression (strong, low), low-level immunosuppression (strong, low), and high-level immunosuppression (strong, very low). Patients should receive PPSV23 ≥ 8 weeks after PCV13, and a second dose of PPSV23 should be given 5 years later (strong, low).
108. VAR should be administered to patients with chronic inflammatory diseases without evidence of varicella immunity (defined in recommendation 15; strong, moderate) ≥ 4 weeks prior to initiation of immunosuppression (strong, low) if treatment initiation can be safely delayed.
109. VAR should be considered for patients without evidence of varicella immunity (defined in recommendation 15) being treated for chronic inflammatory diseases with long-term, low-level immunosuppression (weak, very low).*
110. ZOS should be administered to patients with chronic inflammatory disorders who are aged ≥ 60 years prior to initiation of immunosuppression (strong, low) or being treated with low-dose immunosuppression (strong, very low) and those who are aged 50–59 years and varicella positive prior to initiation of immunosuppression (weak, low)* or being treated with low-dose immunosuppression (weak, very low).*
111. Other live vaccines should *not* be administered to patients with chronic inflammatory diseases on maintenance immunosuppression: LAIV (weak, very low), MMR vaccine in patients receiving low-level (weak, very low) and high-level immunosuppression (weak, very low); and MMRV vaccine in patients receiving low-level (weak, very low) and high-level immunosuppression (strong, very low).
112. Other recommended vaccines, including IIV and HepB vaccine, should *not* be withheld because of concerns about exacerbation of chronic immune-mediated or inflammatory illness (strong, moderate).

Recommendations for Vaccination of Patients with Asplenia or Sickle Cell Diseases

XXII. Which Vaccines Should Be Administered to Asplenic Patients and Those with Sickle Cell Diseases?

113. Asplenic patients and those with sickle cell diseases should receive vaccines including PCV13 for children aged < 2 years, as recommended routinely for immunocompetent persons based on the CDC annual schedule. No vaccine is contraindicated (strong, moderate) except LAIV (weak, very low).
114. PCV13 should be administered to asplenic patients and patients with sickle cell diseases aged ≥ 2 years based on the CDC annual schedule for children and as in recommendations 27a–c (strong, very low-moderate).
115. PPSV23 should be administered to asplenic patients and patients with a sickle cell disease aged ≥ 2 years (strong, low) with an interval of ≥ 8 weeks after PCV13, and a second dose of PPSV23 should be administered 5 years later (strong, low).
116. For PPSV23-naïve patients aged ≥ 2 years for whom a splenectomy is planned, PPSV23 should be administered ≥ 2 weeks prior to surgery (and following indicated dose[s] of PCV13; strong, moderate) or ≥ 2 weeks following surgery (weak, low).*
117. One dose of Hib vaccine should be administered to unvaccinated persons aged ≥ 5 years who are asplenic or have a sickle cell disease (weak, low).
118. Meningococcal vaccine should be administered to patients aged ≥ 2 months who are asplenic or have a sickle cell disease (strong,

low), as in recommendation 29. However, MCV4-D should *not* be administered in patients aged <2 years because of a reduced antibody response to some pneumococcal serotypes when both MCV4 and PCV are administered simultaneously (strong, low). Revaccination with MCV4 (or MPSV4 for those aged >55 years who have not received MCV4) is recommended every 5 years (strong, low).

Recommendations for Vaccination of Patients with Anatomic Barrier Defects at Risk for Infections with Vaccine-Preventable Pathogens

XXIII. Which Vaccinations Should Be Given to Individuals with Cochlear Implants or Congenital Dysplasias of the Inner Ear or Persistent Cerebrospinal Fluid Communication with the Oropharynx or Nasopharynx?

119. Adults and children with profound deafness scheduled to receive a cochlear implant, congenital dysplasias of the inner ear, or persistent cerebrospinal fluid (CSF) communication with the oropharynx or nasopharynx should receive all vaccines recommended routinely for immunocompetent persons based on the CDC annual schedule. No vaccine is contraindicated (strong, moderate).
120. Patients with a cochlear implant, profound deafness and scheduled to receive a cochlear implant, or persistent communications between the CSF and oropharynx or nasopharynx should receive PCV13 as described in the standard schedule for children and recommendations 27a–c (strong, low-moderate).
121. Patients aged ≥24 months with a cochlear implant, profound deafness and scheduled to receive a cochlear implant, or persistent communications between the CSF and oropharynx or nasopharynx should receive PPSV23, preferably ≥8 weeks after receipt of PCV13 (strong, moderate).
122. PCV13 and PPSV23 should be administered ≥2 weeks prior to cochlear implant surgery, if feasible (strong, low).

Definitions:

Strength of Recommendations and Quality of the Evidence			
Strength of Recommendation and Quality of Evidence	Clarity of Balance between Desirable and Undesirable Effects	Methodologic Quality of Supporting Evidence (Examples)	Implications
Strong recommendation, high-quality evidence	Desirable effects clearly outweigh undesirable effects, or vice versa	Consistent evidence from well-performed randomized controlled trials (RCTs) or exceptionally strong evidence from unbiased observational studies	Recommendation can apply to most patients in most circumstances. Further research is unlikely to change confidence in the estimate of effect.
Strong recommendation, moderate-quality evidence	Desirable effects clearly outweigh undesirable effects, or vice versa	Evidence from RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from unbiased observational studies	Recommendation can apply to most patients in most circumstances. Further research (if performed) is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Strong recommendation, low-quality evidence	Desirable effects clearly outweigh undesirable effects, or vice versa	Evidence for at least 1 critical outcome from observational studies, RCTs with serious flaws or indirect evidence	Recommendation may change when higher-quality evidence becomes available. Further research (if performed) is likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Strong recommendation, very low-quality evidence (very rarely applicable)	Desirable effects clearly outweigh undesirable effects, or vice versa	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence	Recommendation may change when higher-quality evidence becomes available; any estimate of effect for at least 1 critical outcome is very uncertain.
Weak recommendation, high-quality evidence	Desirable effects closely balanced with undesirable effects	Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies	The best action may differ depending on circumstances or patients or societal values. Further research is unlikely to change confidence in the estimate of effect.
Weak recommendation, moderate-quality evidence	Desirable effects closely balanced with undesirable effects	Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or	Alternative approaches likely to be better for some patients under some circumstances. Further research (if performed) is likely to have an important

Strength of Recommendation and Quality of Evidence	Strength of Recommendations and Quality of the Evidence		
	Clarity of Balance between Desirable and Undesirable Effects	Methodologic Quality of Supporting Evidence (Examples)	Implications
Strong recommendation, high-quality evidence	Major uncertainty in the estimates of desirable effects, harms, and burden; desirable effects, harms, and burden may be closely balanced	Exceptionally strong evidence from unbiased observational studies or evidence for at least 1 critical outcome from observational studies, RCTs with serious flaws, or indirect evidence	Impact on confidence in the estimate of effect and may change the estimate. Other alternatives may be equally reasonable. Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Weak recommendation, very low-quality evidence	Major uncertainty in the estimates of desirable effects, harms, and burden; desirable effects may or may not be balanced with undesirable effects or may be closely balanced	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence	Other alternatives may be equally reasonable. Any estimate of effect, for at least 1 critical outcome, is very uncertain.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Immunocompromising conditions such as primary (congenital) immune deficiencies, human immunodeficiency virus (HIV) infection, cancer, allogeneic or autologous hematopoietic stem cell transplant (HSCT), solid organ transplant (SOT), chronic inflammatory diseases requiring immunosuppressive medications, asplenia, sickle cell disease, cochlear implantation, or cerebrospinal fluid (CSF) leak
- Vaccine-preventable infectious diseases:
 - Haemophilus influenzae* type b infection
 - Hepatitis A
 - Hepatitis B
 - Diphtheria
 - Tetanus
 - Pertussis
 - Human papillomavirus infection
 - Influenza
 - Measles
 - Mumps
 - Rubella
 - Varicella
 - Meningococcal infection
 - Pneumococcal infection
 - Polio
 - Rotavirus
 - Herpes zoster infection
 - Yellow fever

Guideline Category

Prevention

Clinical Specialty

Allergy and Immunology

Family Practice

Hematology

Infectious Diseases

Internal Medicine

Oncology

Pediatrics

Rheumatology

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide primary care and specialty clinicians with evidence-based recommendations for active vaccination of immunocompromised patients and members of their household in order to safely prevent vaccine-preventable infections, with the ultimate goal of decreasing associated morbidity and mortality

Target Population

- Children and adults with primary (congenital) immune deficiencies
- Patients with secondary immune deficiencies due to human immunodeficiency virus (HIV) infection, cancers associated with immune deficiency, cancer chemotherapy, stem cell or solid organ transplant (SOT), sickle cell diseases, and surgical asplenia
- Patients with chronic inflammatory diseases treated with systemic corticosteroid therapy, immunomodulator medications, and/or biologic agents
- Immunocompetent patients who have an anatomic host defense abnormality (e.g., cerebrospinal fluid [CSF] leak) associated with vaccine-preventable infections
- Individuals living in a household with immunocompromised patients
- Immunocompromised persons contemplating international travel

Note: Vaccination of neonates (including premature neonates), the elderly, burn patients, and pregnant women is beyond the scope of this guideline.

Interventions and Practices Considered

Vaccination with the following:

1. *Haemophilus influenzae* b (Hib) conjugate vaccine
2. Hepatitis A (HepA) vaccine
3. Hepatitis B (HepB) vaccine
4. Diphtheria toxoid, tetanus toxoid, acellular pertussis (DTaP) vaccine
5. Tetanus toxoid, reduced diphtheria toxoid, and reduced acellular pertussis (Tdap) vaccine
6. Tetanus toxoid, reduced diphtheria toxoid (Td) vaccine
7. Quadrivalent human papillomavirus (HPV4) vaccine
8. Inactivated influenza vaccine (IIV)
9. Live attenuated influenza vaccine (LAIV)
10. Measles, mumps, and rubella (MMR) vaccine

11. Varicella (live) vaccine (VAR)
12. Meningococcal conjugate vaccine
13. Pneumococcal conjugate (PCV13) vaccine
14. Pneumococcal polysaccharide (PPSV23) vaccine
15. Inactivated poliovirus vaccine
16. Rotavirus (live) vaccine
17. Zoster (live) vaccine (ZOS)
18. Yellow fever vaccine

Major Outcomes Considered

- Vaccination rate
- Effectiveness of vaccination in preventing infection
- Morbidity and mortality from vaccine-preventable infections in immunocompromised patients
- Adverse effects of vaccination

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The expert panel reviewed and analyzed literature published from January 1, 1966 plus some more recent publications with an end date of July 1, 2012. Computerized English-language literature searches of the National Library of Medicine PubMed database were performed using the terms "vaccination," "vaccine," "immunization," and names of specific vaccines for each patient population or disorder under consideration. Selected references in selected publications were also reviewed. The literature was limited for many vaccines and patient populations and primarily comprised case series evaluating vaccine immunogenicity and safety in particular populations of immunocompromised patients. There were few comparative or efficacy trials described in the literature.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

See the "Rating Scheme for the Strength of the Recommendations" field.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Description of the Methods Used to Analyze the Evidence

The evidence evaluation process was based on the Infectious Diseases Society of America (IDSA) Handbook on Clinical Practice Guideline Development, which involves a systematic weighting of the quality of evidence and the grade of recommendation using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system (see the "Rating Scheme for the Strength of the Recommendations" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Panel Composition

The Infectious Diseases Society of America (IDSA) Standards and Practice Guidelines Committee (SPGC) collaborated with partner organizations and convened a panel of 12 experts in vaccination of immunocompromised patients with a goal of devising recommendations for clinical practice. The panel represented diverse geographic areas, pediatric and adult practitioners, and a wide breadth of specialties (gastroenterology, immunology, infectious diseases, hematology and oncology, rheumatology, and stem cell and solid organ transplantation) and organizations (the Centers for Disease Control and Prevention [CDC]; American College of Rheumatology; North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition; American Academy of Pediatrics [AAP]; Pediatric Infectious Diseases Society; and European Group for Blood and Marrow Transplantation).

Process Overview and Consensus Development Based on Evidence

Panel subgroups reviewed the initial literature search, selected references, evaluated evidence, drafted recommendations, and summarized the evidence for each section. Published guidelines formed the basis for recommendations on vaccination of patients with human immunodeficiency virus (HIV) or hematopoietic stem cell transplant (HSCT), with modifications based on newer references and discussion among panel members.

Drafts were circulated among panel members for commentary and discussed on 14 occasions by teleconference or in-person meeting.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations and Quality of the Evidence			
Strength of Recommendation and Quality of Evidence	Clarity of Balance between Desirable and Undesirable Effects	Methodologic Quality of Supporting Evidence (Examples)	Implications
Strong recommendation, high-quality evidence	Desirable effects clearly outweigh undesirable effects, or vice versa	Consistent evidence from well-performed randomized controlled trials (RCTs) or exceptionally strong evidence from unbiased observational studies	Recommendation can apply to most patients in most circumstances. Further research is unlikely to change confidence in the estimate of effect.
Strong recommendation, moderate-quality evidence	Desirable effects clearly outweigh undesirable effects, or vice versa	Evidence from RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from unbiased observational studies	Recommendation can apply to most patients in most circumstances. Further research (if performed) is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Strong recommendation,	Desirable effects clearly outweigh undesirable effects, or	Evidence for at least 1 critical outcome from observational	Recommendation may change when higher-quality evidence becomes available. Further

low-quality evidence	vice versa	Strength of Recommendations and Quality of the Evidence	research (if performed) is likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Strength of Recommendation and Quality of Evidence	Clarity of Balance between Desirable and Undesirable Effects	Methodologic Quality of Supporting Evidence (Examples)	Implications
Strong recommendation, very low-quality evidence (very rarely applicable)	Desirable effects clearly outweigh undesirable effects, or vice versa	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence	Recommendation may change when higher-quality evidence becomes available; any estimate of effect for at least 1 critical outcome is very uncertain.
Weak recommendation, high-quality evidence	Desirable effects closely balanced with undesirable effects	Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies	The best action may differ depending on circumstances or patients or societal values. Further research is unlikely to change confidence in the estimate of effect.
Weak recommendation, moderate-quality evidence	Desirable effects closely balanced with undesirable effects	Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from unbiased observational studies	Alternative approaches likely to be better for some patients under some circumstances. Further research (if performed) is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Weak recommendation, low-quality evidence	Uncertainty in the estimates of desirable effects, harms, and burden; desirable effects, harms, and burden may be closely balanced	Evidence for at least 1 critical outcome from observational studies, RCTs with serious flaws, or indirect evidence	Other alternatives may be equally reasonable. Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
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Cost Analysis

In one study, influenza vaccination was cost effective in working-age patients with cancer.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Feedback from 3 external peer reviews and endorsing organizations was obtained and used to modify the document. The guideline was reviewed and endorsed by the American Academy of Pediatrics (AAP); American Society of Hematology; American Society of Pediatric Hematology/Oncology; European Group for Blood and Marrow Transplantation; North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition; and Pediatric Infectious Diseases Society. The guideline was reviewed and approved by the Infectious Diseases Society of America (IDSA) Standards and Practice Guidelines Committee (SPGC) and the Board of Directors.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate vaccination of immunocompromised patients and their household contacts
- Prevention of vaccine-preventable infections

Potential Harms

- The decision to administer or withhold a vaccine should be based on balancing the burden of the vaccine-preventable disease and risk of developing severe or life-threatening infection with the wild-type pathogen and the risks of adverse effects from vaccination.
- The risk of posttransplant disease from pretransplant administration of live vaccines such as varicella (VAR), measles, mumps, and rubella (MMR), or zoster (ZOS) vaccines has not been completely defined. A waiting period of 4 weeks was chosen based, in part, on the outer range of risk for developing skin lesions postvaccination for most patients.
- MMR vaccine was safely administered to human immunodeficiency virus (HIV)-infected children with $\geq 15\%$ CD4 T lymphocytes in >1200 patients. However, some severe complications occurred in children with lower CD4 T-cell lymphocyte percentages or counts.
- Data are very limited on yellow fever vaccine in immunocompromised persons. Investigators recently studied the effect of yellow fever vaccine in 70 patients with rheumatic diseases including rheumatoid arthritis, systemic lupus erythematosus, and spondyloarthropathies who were treated with immunosuppressive drugs. Mild adverse effects (e.g., rash, myalgia, elevated hepatic transaminases) occurred in 22.5% of vaccinees, suggesting a reasonably safety profile. However, sample size was inadequate for detecting rare serious complications, and cases of yellow fever vaccine-associated viscerotropic disease have been reported in this population. Yellow fever vaccine has been safely administered to a limited number of post-hematopoietic stem cell transplant (HSCT) patients and to more than 200 HIV-infected adults, the majority of whom had CD4 T-cell lymphocyte counts >200 cells/mm³. An increase in relapse of multiple sclerosis was noted in 7 yellow fever vaccine recipients.
- Administration of inactivated vaccines to HIV-infected persons appears safe as no increases in adverse effects or HIV-specific adverse effects have been recognized. However, data are not sufficient to comment on rare adverse effects.
- In the United States, diphtheria toxoid in combination with tetanus toxoid (DT) vaccine is not approved for persons aged >6 years due to adverse effects. However, experience with adult HSCT recipients indicates a lower risk for adverse effects than in previously vaccinated immunocompetent adults, suggesting that the adverse effect profile of DT vaccine may be acceptable in this population. It has not yet been determined whether the immune response to tetanus toxoid, reduced diphtheria toxoid vaccine (Td) is equivalent to the response to DT vaccine.

Contraindications

Contraindications

- Live attenuated influenza vaccine (LAIV) is contraindicated for asplenic patients, immunocompromised patients, and those with sickle cell diseases.
- Live vaccines are generally contraindicated in immunodeficient patients because attenuation is relative.
- Oral polio vaccine (OPV) is contraindicated for patients with severe combined immune deficiency (SCID) because paralytic poliomyelitis has occurred after vaccination.
- Varicella vaccine (VAR) is generally considered contraindicated for children with inflammatory bowel disease (IBD) who are receiving 6-mercaptopurine.
- Live, attenuated, cold-adapted intranasal influenza vaccine is not administered to immunocompromised patients based on insufficient clinical data to support these judgments.
- Certain immunocompromised patients may have thrombocytopenia that may be a relative contraindication to an intramuscular injection.
- In general, live vaccines are contraindicated in human immunodeficiency virus (HIV)-infected persons with low CD4 T-cell lymphocyte counts or percentages.

- Live viral vaccines are contraindicated during chemotherapy because of the risk of disseminated disease.
- Many molecular defects can result in defects of antiviral immunity, contraindicating the use of live viral vaccines.
- The use of bacillus Calmette-Guérin (BCG) vaccine is contraindicated in hematopoietic stem cell transplant (HSCT) recipients because it is a live bacterial vaccine with a potential risk of serious adverse effects.

Tables 2-7 in the original guideline document provide additional information on contraindications in specific clinical contexts.

Qualifying Statements

Qualifying Statements

- It is important to realize that guidelines cannot always account for individual variation among patients. The guidelines are not intended to supplant physician judgment with respect to particular patients or special clinical situations. The Infectious Diseases Society of America (IDSA) considers adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in the light of each patient's individual circumstances.
- Data on safety, immunogenicity, and efficacy/effectiveness of vaccines for immunocompromised populations are limited. Preliminary studies often exclude immunocompromised persons, and postlicensure studies examine small numbers of immunocompromised patients. These small numbers are problematic when assessing adverse effects. Furthermore, immune defects vary among and within categories of patients with immune deficiencies (e.g., degree of immune deficiency, nutritional status, immunosuppressive regimen), which may limit the generalizability of study findings.
- This guideline addresses vaccines routinely recommended on the basis of patient age, social or occupational history, increased risk of infection related to underlying disease or treatment of disease, and travel. Vaccines for bioterrorism are not addressed. Immunobiological agents administered for active vaccination are addressed; immune globulin preparations and monoclonal antibodies used for passive vaccination are not. This guideline focuses on vaccines available in the United States, which are often relevant to other areas. Informed consent prior to vaccination, including provision of a Centers for Disease Control and Prevention (CDC) vaccine information statement, documentation of the vaccination, communication about vaccination to the patient (parent) or to clinicians involved in the patient's care, and discussion of vaccination registries, is beyond the scope of this document.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

Pocket Guide/Reference Cards

For information about availability, see the *Availability of Companion Documents and Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Rubin LG, Levin MJ, Ljungman P, Davies EG, Avery R, Tomblyn M, Bousvaros A, Dhanireddy S, Sung L, Keyserling H, Kang I. 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host. Clin Infect Dis. 2014 Feb;58(3):e44-e100. [484 references] [PubMed](#)

Adaptation

The guidelines for vaccination of hematopoietic stem cell transplant (HSCT) candidates and recipients have been adapted from the following source: Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: a global perspective. Biol Blood Marrow Transplant 2009; 15:1143–238.

Date Released

2014 Feb

Guideline Developer(s)

Infectious Diseases Society of America - Medical Specialty Society

Source(s) of Funding

The Infectious Diseases Society of America provided support for this guideline.

Guideline Committee

Infectious Diseases Society of America (IDSA) Standards and Practice Guidelines Committee (SPGC)

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Financial Disclosures/Conflicts of Interest

Guidelines and Conflict of Interest

All panel members complied with the Infectious Diseases Society of America (IDSA) policy on conflict of interest, which requires disclosure of any financial or other interest that might be construed as constituting an actual, potential, or apparent conflict. They were provided IDSA's conflict-of-interest disclosure statement and asked to identify ties to companies that develop products that might be affected by promulgation of the guideline. Information was requested regarding employment, consultancies, stock ownership, honoraria, research funding, expert testimony, and membership on company advisory committees. The panel decided on a case-by-case basis whether conflict should limit member participation.

Potential Conflicts of Interest

The following list is a reflection of what has been reported to the IDSA. In order to provide thorough transparency, the IDSA requires full disclosure of all relationships, regardless of relevancy to the guideline topic. Evaluation of such relationships as potential conflicts of interest is determined by a review process that includes assessment by the Standards and Practice Guidelines Committee (SPGC) chair, the SPGC liaison to the development panel, the Board of Directors liaison to the SPGC, and, if necessary, the Conflict of Interest Task Force of the board. This assessment of disclosed relationships for possible conflict of interest is based on the relative weight of the financial relationship (i.e., monetary amount) and the relevance of the relationship (i.e., the degree to which an association might reasonably be interpreted by an independent observer as related to the topic or recommendation of consideration). The reader of these guidelines should be mindful of this when the list of disclosures is reviewed. R. A. has served as a subinvestigator on clinical trials funded by ViroPharma, Roche, and the CDC. A. B. has served as a subinvestigator on clinical trials funded by Abbott, UCB, and Merck; served as a consultant to Dyax, Cubist, and Nutricia; received speaking fees from Merck; and received a writing honorarium from Up-To-Date, Inc. E. G. D. has served as a consultant with GlaxoSmithKline and received a grant from Pfizer. I. K. has received research funding from Amino Up Chemical. H. K. has received funding from Pfizer for a clinical trial. M. L. has served as a consultant for Merck, MedImmune, and GlaxoSmithKline; has received honoraria and patent license from Merck; is on an adjudication committee for GlaxoSmithKline; and participates in research studies with Sanofi Pasteur, GlaxoSmithKline, and Merck. P. L. has served as a consultant to ViroPharma, Vical, Clinigen, Astellas Pharma, and Pfizer; served as an investigator for ViroPharma, Astellas Pharma, Pfizer, and Merck; and chaired a Data and Safety Monitoring Board for AiCuris. No conflicts: G. A., L. R., S. D., M. T., L. S., and E.W. All other authors report no potential conflicts.

All authors have submitted the International Committee of Medical Journal Editors (ICMJE) Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

Guideline Endorser(s)

American Academy of Pediatrics - Medical Specialty Society

American Society of Hematology - Medical Specialty Society

American Society of Pediatric Hematology/Oncology - Professional Association

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition - Professional Association

Pediatric Infectious Diseases Society - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the [Clinical Infectious Diseases Web site](#) .

Availability of Companion Documents

The following is available:

- Vaccination of the immunocompromised host. Pocket card. Electronic copies: Available from the [Infectious Disease Society of America \(IDSA\) Web site](#) . Also available for mobile devices from the [IDSA Web site](#) .

Patient Resources

None available

NGC Status

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